

Appl. No. 10/089,058  
Response dated October 27, 2005  
Reply to Office action of June 28, 2005

### **REMARKS**

By the present amendment, claims 1-12, 22-26, 39-41, 43-44 and 46-47 have been withdrawn, claims 13, 42 and 45 have been amended, claims 14 and 21 have been cancelled and new claim 48 has been added which is directed to a specific embodiment. Claims 13, 15-20, 37-38, 42, 45 and 48, are pending in the application. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. No new matter has been entered by the present amendment and its entry is respectfully requested.

The Official Action dated June 28, 2005 has been carefully considered. It is believed that the amended specification and claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **Claim Objections**

The Examiner has objected to claims 21 and 42 as exceeding the maximum number of sequences that are permitted to be claimed in single application. In response, claim 21 has been deleted and claims 13 and 42 have been amended in order to recite only ten sequences. Applicant notes a slight difference in the list of 10 sequences as compared to the list provided in the response to the Restriction Requirement filed April 11, 2005. Specifically, SEQ ID NO:7 is not included in the current list and was replaced by SEQ ID NO:56. The initial selection of SEQ ID NO:7 instead of SEQ ID NO:56 was an oversight.

The Examiner has objected to claim 14 in light of the abbreviations "MMP" and "UPA". In response, claim 14 has been deleted in light of the amendment to claim 13 to recite specific sequences.

### **35 U.S.C § 112**

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The Examiner has objected to claims 13, 15-21, 37-38, and 45 under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Specifically, the Examiner comments that these claims recite a recombinant protein having a linker sequence which contains a cleavage recognition site for a "specific protease". In response, claim 13 has been amended in order to recite ten specific sequences that have support in the specification.

The Examiner has objected to claims 13-21, 37-38, and 45 under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. Specifically, the Examiner comments that these claims recite a recombinant protein having an A chain of a "ricin like toxin" and a B chain of a "ricin-like toxin". We respectfully disagree with the Examiner as the specification provides clear guidance as to which types of proteins would be considered "ricin-like" proteins. Specifically, we refer to pages 18 and 19 of the application as filed. Further, we point out that Applicant is not claiming novel toxins *per se* but rather novel recombinant proteins containing an A chain and a B chain of a ricin-like toxin linked by a novel linker sequence that contains a cleavage recognition site for a specific protease. We also point out that the language "ricin-like toxin" has been considered in prosecution of the related cases and allowed by the United States Patent Office. In this regard, we refer to related U.S. Patent Nos. 6,333,303 and 6,531,125.

In view of the foregoing, we respectfully request that the objections to the claims under U.S.C § 112, first paragraph be withdrawn.

35 U.S.C § 102

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The Examiner has objected to claims 13-20 and 37-38 under 35 U.S.C § 102(a) as being anticipated by Borgford (WO 98/49311). As mentioned previously, by the present amendment, claim 13 has been amended in order to specify linker sequences that were present in previous claim 21. None of the sequences are disclosed in Borgford and therefore Borgford cannot be said to anticipate the claims.

In view of the foregoing, we respectfully request that the objections to the claims under 35 U.S.C § 102(a) be withdrawn.

The Examiner has objected to claims 13, 15-20 and 37-38 under 35 U.S.C § 102(b) as being anticipated by Borgford (WO 97/41233). As mentioned above, the claims have been amended to recite specific linker sequences. None of the sequences are disclosed in Borgford and therefore Borgford cannot be said to anticipate the claims.

In view of the foregoing, we respectfully request that the objections to the claims under 35 U.S.C § 102(b) be withdrawn.

### **35 U.S.C § 103**

The Examiner has objected to claims 13-20 and 37-38 as being unpatentable over Borgford (WO 97/41233) in view of Kappler et al.

As mentioned previously, the claims of the present invention have been amended to specify specific linker sequences. None of the specific sequences are disclosed in Borgford. The deficiencies in Borgford are not remedied by Kappler et al. which in no way discloses or remotely suggests the novel linker sequences of the present invention. Neither Borgford nor Kappler provides motivation to one of skill in the art to prepare novel linkers.

We note that claim 21 was not included in the objection and that independent claim 13 has been amended to incorporate the subject matter of claim 21.

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In view of the foregoing, we respectfully request that the objections to the claims under 35 U.S.C § 103(a) be withdrawn.

**Double Patenting**

The Examiner has objected to claims 13-21, 37-38, 42 and 45 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,333,303; claims 1-24 of U.S. Patent No. 6,531,125; and claims 1-4 of U.S. Patent No. 6,803,358.


As the claims of the present invention have been amended in order to specify novel sequences that are not disclosed or suggested in the related patents we submit that the current claims are not obvious over the related patents.

In view of the foregoing, we respectfully request that the double patenting rejection be withdrawn.

The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1682 at his convenience.

Respectfully submitted,  
BERESKIN & PARR

By   
Micheline Gravelle  
Reg. No. 40,261

Bereskin & Parr

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Box 401, 40 King Street West  
Toronto, Ontario  
Canada M5H 3Y2  
Tel: 416-957-1682  
Fax: 416-361-1398